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PATENT 1600/2900
Docket No. 2026-4116US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#9

Applicant(s) : Bukh, et al. Group Art Unit: 1631
Serial No. : 09/084,691 Examiner : Zeman, M.
Filed : May 26, 1998
For : NUCLEOTIDE AND DEDUCED AMINO ACID SEQUENCES OF THE ENVELOPE 1 AND CORE GENES OF ISOLATES OF HEPATITIS C VIRUS AND THE USE OF REAGENTS DERIVED FROM THESE SEQUENCES IN DIAGNOSTIC METHODS AND VACCINES

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated October 13, 2000, the Examiner restricted the claims of the invention into the following groups:

- I. Claims 1, 3, 6-10, 17, 20, 47, 48, 50 and 51 drawn to polynucleotides, expression vectors, viral vaccine vectors, methods of producing a recombinant polypeptide;
- II. Claims 4, 5, 16, 19, 32, 38, 43, 44, 46, drawn to compositions comprising core polypeptides, and claims 15, 37, drawn to kits comprising those polypeptides and claims 11-14, 33-36, 39-42, and 59 drawn to methods of using those polypeptides to detect antibodies;
- III. Claims 21-25, drawn to methods of detecting HCV in a sample using universal primers, and compositions comprising those primers;

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- IV. Claims 26-32, drawn to methods of determining the genotype of an HCV in a sample, and compositions comprising genotype specific primers;
- V. Claims 18, 45, 49, drawn to methods of preventing HCV infection; and
- VI. Claims 52-58, drawn to core or env antibodies and methods of using them in an immunoassay.

In reply, Applicants respectfully elect the claims of Group II, claims 4, 5, 16, 19, 32, 38, 43, 44, 46, drawn to compositions comprising core polypeptides, claims 15 and 37, drawn to kits comprising core polypeptides, and claims 11-14, 33-36, 39-42, and 59 drawn to methods of using core polypeptides to detect antibodies.

Further, the Examiner stated on page 5 of the restriction requirement that if the invention of Group II was elected, then the Applicants must also elect the following species:

a) env sequences or b) core sequences;

followed by a further election of:

i) universal peptide sequences or ii) genotype specific sequences;

and finally:

a single polypeptides sequence SEQ ID NO., corresponding to either a universal or a genotype specific sequence.

Applicants thank the Examiner for her generous assistance in the telephone conference held on December 6, 2000, where the Examiner agreed that Applicants may elect a species and SEQ ID NO. corresponding to a whole core gene sequence, rather than a single universal or genotype specific peptide sequence within the whole core gene. In view of this, Applicants elect the species of core sequences (Applicants note that the Group II invention is already limited to core polypeptide sequences), followed by a further species election of the whole core polypeptide sequence of HCV major genotype 6, corresponding to SEQ ID NO. 206. Currently, all Group II claims, 4, 5, 11-16, 19, 32-44, 45 and 59, read on the elected species.

In the December 6, 2000 telephone conference, the Examiner requested that the Applicants point out which regions within the whole genotype 6 core gene correspond to universal and genotype specific peptide sequences. In reply, Applicants note that the chart on page 57 of the specification shows examples of genotype 6 core sequence domains from which genotype specific peptides may be deduced (e.g. amino acid regions 67-78, 101-108, 144-155, and 157-163). In addition, the chart on page 59 of the specification shows examples of universally conserved core amino acid domains of genotype 6 from which universal peptide sequences may be deduced (e.g. amino acid regions 23-35, 53-66, 93-108, 122-138, 150-156, and 165-181).

Finally, Applicants respectfully submit that upon allowance of the generic claim 4, Applicants will be entitled to consideration of claims drawn to additional species of core

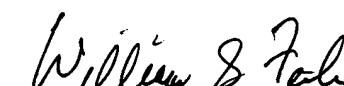
sequences which are written in dependent form, or otherwise include all of the limitations of claim 4 as provided by 37 C.F.R. 1.141.

Respectfully submitted,

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Dated: December 13, 2000

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